



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[60Day-12-12AM]
Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation (U01) - New - National Center for Environmental Health (NCEH) and Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Navajo Nation includes 16 million acres of New Mexico, Utah and Arizona. It is the largest Alaska Native/American Indian Reservation in the United States. From 1948 to 1986, many uranium mining and milling operations took place in the Navajo Nation, leaving a large amount of uranium contamination on the reservation. Several studies have reported that uranium mostly damages the kidneys and urinary system. However, there is not much research data on uranium exposure and poor birth and reproductive health outcomes. Research involving prenatal exposure to uranium may help to understand and prevent some unfavorable child and maternal health outcomes.

There are important health differences concerning birth outcomes and prenatal care in the Navajo Nation. According to

the Indian Health Service *Regional Differences in Indian Health 2002-2003 Edition*, the infant death rate among the Navajo people is 8.5 deaths per 1000 live births, compared to 6.9 deaths per 1000 live births among all races. Only 61% of Navajo mothers with live births received prenatal care in the first trimester as compared to 83% of all US mothers. Early and regular prenatal care is a major predicator of positive birth outcomes. Due to the health differences in birth outcomes and the chance for environmental uranium exposure in the Navajo Nation, ATSDR decided that the upcoming study must include education of women and their families about the importance of prenatal care and the potential poor health risks associated with exposure to uranium.

The House Committee on Oversight and Government Reform requested that federal agencies develop a plan to address health and environmental impacts of uranium contamination in the Navajo Nation. As a result of this request, ATSDR awarded a research cooperative agreement to University of New Mexico Community Environmental Health Program (UNM-CEHP) entitled "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation (U01)," in August 2010. ATSDR and UNM-CEHP are working with the Navajo Area Indian Health Service (NAIHS), Navajo Nation Division of Health (NNDOH), Navajo Nation Environmental Protection Agency (NNEPA), and Navajo culture and language specialists to carry out the study. The study will

examine reproductive outcomes in pregnant women, follow and assess their children from birth to 1 year of age, and create a system to follow up the infants through childhood up to 6 years of age to evaluate the impact of uranium exposure on biological and psychosocial endpoints. Biological sample analysis, surveys, and developmental screenings will be performed during this research period for each participant.

In addition to investigating the role of uranium and other chemicals in the environment on birth outcomes and development, the prospective study may aid in understanding causes and prevention measures of chronic conditions. Several research studies have shown that exposure to chemicals in the environment during prenatal and postnatal periods can affect the development of adult chronic diseases. The study will also provide broad public health benefits for Navajo communities through outreach and education on environmental prenatal risks and early assessment. Referrals will also be provided for known developmental delays.

Participants will include Native American mothers from age 14 to 45 with verification of pregnancy who have lived in the study area for at least 5 years. Also, participants must consent to receive prenatal care and deliver at one of the healthcare facilities that are taking part in the study (Northern Navajo Medical Center, Chinle Comprehensive Health Care Facility,

Gallup Indian Medical Center, Tuba City Regional Health-Care Corporation, or Tséhootsooí Medical Center). Fathers will be included in the study with consent regardless of age or residence. We estimate that 550 pregnant women and fathers per year must be enrolled in the study to obtain adequate statistical power. A 10% pregnancy loss will be assumed, which would result in 500 live births per year. Therefore, the total anticipated sample size is 1,500 mother-infant pairs over the three years of the study.

The survey instruments for pregnant mothers include the following: Enrollment Survey, Nutritional Assessment/Food Intake Questionnaire, Ages and Stages Questionnaire (ASQ-I), Mullen Stages of Early Development (MSEL), and Postpartum Surveys. An enrollment survey for fathers who agree to participate will also be administered. Community Health and Environmental Research Specialists (CHERS) will administer surveys using a CDC-approved electronic data entry system. Survey instruments were designed to collect demographic information, assess potential environmental health risks, and mother-child interactions. The survey instruments were developed based on previous surveys conducted by Dine' Network for Environmental Health (DiNEH) Project, the National Children's Study, and by other birth cohort studies that have been conducted among other indigenous populations. The final format of the survey instruments was

modified based on review and input from the Navajo Nation community liaison group and associated Navajo staff to address issues such as cultural sensitivity, comprehension and language translation.

There is no cost to the respondents other than their time to participate in the study. The total estimated annual burden hours equals 3550.

Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden Response (Hours) | Total Burden (Hours) |
|--------------------|---|-----------------------|------------------------------------|---------------------------------|----------------------|
| Mother | Enrollment Survey | 550 | 1 | 2 | 1100 |
| | Ages and Stages Questionnaire (2,6,9 12 months) | 500 | 4 | 15/60 | 500 |
| | Mullen Stages of Early Development | 500 | 1 | 15/60 | 125 |
| | Postpartum Survey (0 months) | 500 | 1 | 1 | 500 |
| | Post-partum Survey (2,6,9,12 months) | 500 | 4 | 15/60 | 500 |
| Father | Enrollment Survey | 550 | 1 | 90/60 | 825 |
| | | | | Total | 3550 |

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